K010208

FEB 2 0 2001

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

Dimension® Enzymatic Carbonate (ECO2) Calibrator (DC137)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR§807.92.

Submitter's Name:	Richard M. Vaught Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101
Date of Preparation:	January 22, 2001
Name of Product:	Dimension® Enzymatic Carbonate (ECO2) Calibrator (DC137)
FDA Classification Name:	Calibrator (21 CFR§862.1150); 75JIT
Predicate Device:	Dade Behring aca® Carbon Dioxide Calibrator for the aca® discrete clinical analyzer.
Device Description:	The Dimension® Enzymatic Carbonate (ECO2) Calibrator is an aqueous product, supplied as a set of 6 ampules, 2 each at 3 levels. Level 1 contains 0.05 HCL; Levels 2 and 3 contain reagent grade sodium carbonate (Na_2CO_3) referenced to National Institute of Standards Technology (NIST).
Intended Use:	The Dimension® Enzymatic Carbonate (ECO2) Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Enzymatic Carbonate (ECO_2) method on the Dimension® clinical chemistry system.

Comparison to Predicate Device:

	Dimension® **Enzymatic Carbonate Calibrator**	**aca®** **Carbon Dioxide Calibrator**
Intended Use:	Calibration of ECO2 (enzymatic total carbon dioxide) method	Calibration of CARB (total carbon dioxide) method
Analytes:	Sodium carbonate (Na_2CO_3)	Sodium carbonate (Na_2CO_3)
Form:	weighed-in; aqueous solution	weighed-in; aqueous solution
Levels:	3 levels, ampules	3 levels, ampules

Comments on Substantial Equivalence:

Both the Dade Behring Dimension® Enzymatic Carbonate (ECO2) Calibrator and the Dade Behring aca® Carbon Dioxide (K780295) Calibrator products are intended to calibrate for total carbon dioxide. Both are supplied as aqueous solutions containing weighed-in sodium carbonate of known purity.

Conclusion:

The Dimension® Enzymatic Carbonate (ECO2) Calibrator is substantially equivalent to the aca® carbon dioxide calibrator based on its design and intended use.

R M Vaught

Richard M. Vaught
Regulatory Affairs and Compliance Manager
Date: January 22, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 0 2001

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714

Re: K010208
Trade Name: Dimension ® Enzymatic Carbonate (ECO2) Calibrator
Regulatory Class: II
Product Code: JIT
Dated: January 22, 2001
Received: January 23, 2001

Dear Mr. Vaught

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: K010208

Dimension® Enzymatic Carbonate (ECO2) Calibrator

Indications for Use:

The Enzymatic Carbonate (ECO2) Calibrator for the Dimension® clinical chemistry system is a device intended for medical purposes to establish points of reference that are used in determination of values in the measurement of substances in human specimens.

vision Sign-Off)
vision of Clinical Laboratory Devices
0(k) Number K 010208

Richard M. Vaught
Regulatory Affairs and Compliance Manager

January 22, 2001

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)